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May 23, 2003

3M

By Hand Delivery

mL# 266985

Document Processing Center (7407)
Office of Pollution, Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N. W.
Washington, DC 20460
Attention: Section 8(e) Coordinator

Re: **TSCA Section 8(e) Submissions**

Dear Sir/Madam:

3M Company ("3M") requests that EPA place the attached studies in the TSCA Section 8(e) docket. We have included an index for these studies identifying the study title, test substance and CAS number. A CBI version of this index and the studies also is being submitted today pursuant to EPA procedures.

3M has concluded that data in these studies may not be, strictly speaking, "corroborative" of previously reported or published information as defined in EPA's reporting guidance or otherwise potentially may warrant 8(e) submission based on EPA's reporting guidance.

3M appreciates EPA's attention to this matter. Please contact the undersigned if you have any questions or require further information regarding this submission.

Very truly yours,

Dr. Katherine E. Reed (9M)

Dr. Katherine E. Reed, Ph.D
Executive Director
3M Environmental Technology
And Safety Services
(651) 778-4331
kereed@mmm.com

CONTAINS NO CONFIDENTIAL BUSINESS INFORMATION

SUBMISSION BY 3M COMPANY ON MAY 23, 2003

1.	Exploratory 28-Day Oral Toxicity Study with T-7250, T-7251, T-7252, T-7253, T-7254, and T-7255 by Daily Gavage in the Rat Followed by a 14/28-Day Recovery Period (NOTOX Project 264656)	Separate studies for each chemical: [CBI removed]; Hexanesulfonamide, 1,1,2,2,3,3,4,4,5,5,6,6,6 - Tridecafluoro-n-(2-Hydroxyethyl)-N-Methyl - 100%; 1-Butanesulfonamide, 1,1,2,2,3,3,4,4,4-Nonafluoro-N-n(2-Hydroxyethyl)-N-Methyl - 100%	[CBI removed]; 68555-75-9; 34454-97-2
2.	Exploratory 28-Day Oral Toxicity Study with T-7125, T-7126, T-7127, T-7128, and T-7129 by Daily Gavage in the Rat Followed by a 14/28-Day Recovery Period (NOTOX Project 256679)	Cyclohexanesulfonic acid, decafluoro(pentafluormethyl)-, potassium salt (CAS No. 67584-42-3) - 66-70%; Cyclohexanesulfonic acid, decafluoro(trifuloromethyl)-, potassium salt (CAS No. 68156-07-0) - 18-22%; Cyclohexanesulfonic acid, nonafluorobis(trifluoromethyl)-, potassium salt (CAS No. 68156-01-4) - 9-13%; Cyclohexanesulfonic acid, undecafluoro-, potassium salt (CAS No. 3107-18-4) - 1-3%	67584-42-3; 68156-07-0; 68156-01-4; 3107-18-4
3.	Subchronic 90-Day Oral Toxicity with T-6524 by Daily Gavage in the Rat Followed by a 28-Day Recovery Period	65% Sulfonamides, C4-8-alkane, perfluoro, N-(3-(dimethyloxidoamino)propyl), potassium CAS#179005-06-2; 20% Amine oxide C8F17SO2NH(->O)CH2CH2CH2N(CH3)2; 15% C3-C7 K-salts of amine oxides CNF2N+1SO2N-)(+K)(->O)CH2CH2CH2N(CH3)2	179005-06-2
4.	A Study for Effects on Embryofoetal Development of the Rat (Inhalation Administration)	[CBI removed]	[CBI removed]
5.	Evaluation of the Ability of T-5870 to Induce Chromosome Aberrations in Cultured Peripheral Human Lymphocytes (with Independent Repeat)	2-ethoxy ethyl acrylate	106-74-1
6.	Chromosomal Aberration Test of T-6695 Using Cultured Mammalian Cells	[CBI removed]	[CBI removed]
7.	Acute Oral Toxicity Study in Rats (Exp. No. 920584) (Test Article: Intermedio 1249)	2-methyl-2-butanone-(4-sulfonamidophenyl)-hydrazone; Molecular Formula: C11H17N3O2S	Unknown
8.	Acute Oral Toxicity Study in Rats (Exp. No. 930321) (Test Article: 501149)	3H-pyrazol-3-0ne, 2-(4-aminophenyl), 4-dihydro-5-(1-pyrrolidinyl)	30707-77-8
9.	Skin Corrosivity Study of T-5799 in Rabbits (DOT/UN Regulations)	1-Octanesulfonyl Fluoride - 87.5%, Other Alkyl Sulfonyl Fluorides and Acidic Impurities - 11%, Water - 5.4%, Octanesulfonyl Chloride - 1.4%	40630-63-5; Unknown; 7732-18-5; 7795-95-1
10.	Skin Corrosivity Study of T-5800 in Rabbits (DOT/UN Regulations)	1-Octanesulfonyl Fluoride - 87.5%, Other Alkyl Sulfonyl Fluorides and Acidic Impurities - 11%, Water - 5.4%, Octanesulfonyl Chloride - 1.4%.	40630-63-5; Unknown; 7732-18-5; 7795-95-1
11.	Primary Dermal Irritation/Corrosion Study of T-5635 in Rabbits (OECD Guidelines)	[CBI removed]	[CBI removed]
12.	Primary Dermal Irritation/Corrosion Study of T-5897 in Rabbits (OECD Guidelines)	Isophthaloylbis (2-methylarziridine) - 97%, Toluene - 2%, Xylene - 0.5%.	7652-64-4; 108-88-3; 1330-20-7
13.	Skin Corrosivity Study of T-7030.1 in Rabbits (with Protocol TP4206 attached)	[CBI removed]	[CBI removed]
14.	Dermal Sensitization Study of T-5474 in Guinea Pigs - Maximization Test (EPA Guidelines)	Water (CAS No. 7732-18-5) - 68.4%; Dodecylbenzenesulfonic Acid (CAS No. 27176-87-0) - 17.5%; Polymethacrylate (CAS No. 25087-26-7) - 11.76%; Sodium Hydroxide (CAS No. 1310-73-2) - 2.3%; Unknown - 0.040%	7732-18-5; 27176-87-0; 25087-26-7; 1310-73-2

SUBMISSION BY 3M COMPANY ON MAY 23, 2003

		Test Substance	CAS Number
15	Dermal Sensitization Study of T-5894 in Guinea Pigs - Maximization Test (EC Guidelines) (with Protocol TP6164E attached)	[CBI removed]	[CBI removed]
16.	Dermal Sensitization Study of T-6006 in Guinea Pigs - Closed Patch Technique (EPA Guidelines)	Dimethyltetradecylamine Oxide - 55%, Oleamidopropyldimethylamine - 18%, 1-Methoxy -2-Propanol – 5%, Citronellol – 5%, Polyethylene Glycol - < 3%, Alpha - (Carboxymethyl) - Omega - (Dodecyloxyl) Poly (Oxyethylene) Sodium Salt - ~3%, Trialkyl Amine Oxide - 2%, Isopropyl Alcohol - 2%, Fragrance Sozio SZ 5467 - 2%, Water - 1%, Acetic Acid – 1%, Miscellaneous ingredients at less than 1%	3332-27-2; 109-28-4; 107-98-2; 106-22-9; 25322-68-3; 33939-64-9; 7128-91-8; 67-63-0; Unknown; 7732-18-5; 64-19-7
17.	Dermal Sensitization Study of T-7280 in Guinea Pigs - Closed Patch Technique (with Protocol TP2008 attached)	[CBI removed]	[CBI removed]
18.	Acute Oral Toxicity Study of T-6735 in Rats (OECD Guidelines) (with Protocol TP2069 attached)	4,6-dibromo-2-isopropyl phenol	Unknown
19.	Acute Toxicity to Daphnia Magna	[CBI removed]	[CBI removed]
20.	Evaluation of the Mutagenic Activity of T-5870 in an In Vitro Mammalian Cell Gene Mutation Test with L5178Y Mouse Lymphoma Cells (with Independent Repeat)	2-ethoxy ethyl acrylate	106-74-1
21.	Acute Eye Irritation Study in New Zealand White Rabbits (Exp. No. 920364) (Test Article: 586442-50055)	HP=Benzothiazolium (9CI); SB=3-ethyl-2-((3-(3-(3-ethyl-2(3H)-benzothiazolylidene)-1-propenyl)-5,5-dimethyl-2-cyclohexen-1-ylidene)methyl)-6-methoxy-5-methyl-; NM=Iodide; Molecular Formula: C32H37N2OS2.I	87699-86-3
22.	Acute Eye Irritation Study in New Zealand White Rabbits (Exp. No. 940151) (Test Article: 580066)	Thiazolium, 3-ethyl-2-[3-(3-ethyl-2-thiazolidinylidene)-1-propenyl]-4,5-dihydro-,iodide; Molecular Formula: C13H21N2S2.I	3065-71-2
23.	Acute Eye Irritation Study in New Zealand White Rabbits (Exp. No. 930529) (Test Article: 1268)	3-ethoxy-carbonyl-methyl-4-etoxy-methylidene-rhodanine; Molecular Formula: C10H13NO4S2	Unknown
24	Acute Eye Irritation Study in New Zealand White Rabbits (Exp. No. 920582) (Test Article: 1248)	C6H10ClN3O2S	Unknown
25.	One Generation Reproduction Study of PFOS - Mevalonic Acid/Cholesterol Challenge and NOEL Investigation in Rats	Perfluorooctane Sulfonic Acid Potassium Salt	2795-39-3
26	Augmented acute (4-hour) inhalation toxicity study with T-6905 in rats	2% solids of fluorochemical fatty acid ester in water	306974-63-0

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FINAL REPORT

Roger G. Perkins, PhD
3M
Toxicology Services
Building 220-2E-02
St. Paul, MN 55144-1000

HWI Number: 40202402

Study Title:

Primary Dermal Irritation/Corrosion
Study of T-5897 in Rabbits
(OECD Guidelines)

Signed: _____ 5-6-94
Steven M. Glaza
Study Director
Acute Toxicology

Date

Phone 608-241-4471 Fax 608-241-7227
FOR EXPRESS-MAIL DELIVERY: 3301 KINSMAN BOULEVARD, MADISON, WISCONSIN 53704

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   The term "None Detected" is used to report assay results where detection limits have been established for the method but acceptable residue levels have not been defined by the industry or by federal law or when the method does not define detection limits. The term will specify the fixed amount of sample employed in the analysis and does not imply that traces of the analyte were present.

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KEY PERSONNEL

Acute Toxicology

Steven M. Glaza
Study Director
Manager

Steven R. Sorenson
Study Coordinator

Patricia Padgham
In-life Supervisor

Rose M. Bridge
Report Supervisor

Laboratory Animal Medicine

Cindy J. Cary, DVM
Diplomate, ACLAM
Supervisor

CONTENTS

OBJECTIVE

The objective of this study was to assess the relative level of primary skin irritation/corrosion of a test material on rabbits under semioccluded conditions.[1]

All procedures used in this study are in compliance with the Animal Welfare Act Regulations. In the opinion of the Sponsor and study director, the study did not unnecessarily duplicate any previous work.

TEST MATERIAL

Identification

The test material was identified as T-5897 and described as a viscous, cloudy, white liquid (at ambient temperature).

Purity and Stability

The Sponsor assumes responsibility for purity and stability determinations (including under test conditions).

Storage and Retention

The test material was stored frozen. Any unused test material will be returned to the Sponsor after issuance of the final report according to Hazleton Wisconsin (HWI) Standard Operating Procedure (SOP).

Safety Precautions

The test material handling procedures were according to HWI SOPs and policies.

TEST SYSTEM

Test Animal

Adult albino rabbits of the Hra:(NZW)SPF strain were procured from HRP, Inc. and maintained at the Hazleton Wisconsin facility at 3802 Packers Avenue, Madison, Wisconsin. Animal husbandry and housing at HWI comply with standards outlined in the "Guide for the Care and Use of Laboratory Animals".[2] The animals were individually housed in screen-bottom cages in temperature- and humidity-controlled quarters, provided access to water *ad libitum* and a measured amount of Laboratory Rabbit Diet HF #5326, PMI Feeds, Inc., and held for an acclimation period of at least 7 days. The feed is routinely analyzed by the manufacturer for nutritional components and environmental contaminants.

Samples of the water are periodically analyzed by HWI. There were no known contaminants in the feed or water that would have interfered with or affected the results of the study.

Three female acclimated animals, weighing from 2,012 to 2,185 g, were selected and maintained during the study in the same manner as for the acclimation period. If variations from the required temperature and humidity conditions existed, they were documented and considered to have had no adverse effect on the study outcome. Animals were identified by animal number and corresponding ear tag. On the day before treatment, the back and/or flanks of each animal were clipped free of hair to obtain an unblemished skin site. The animals were clipped as needed throughout the study.

Justification for Species Selection

Historically, the New Zealand White albino rabbit has been the animal of choice for evaluating the effect of chemicals on the skin.

PROCEDURES

Preparation of Test Material

The test material was brought to room temperature and administered as received. The pH of the test material was not able to be determined.

Treatment

The test material was applied to the intact skin on each animal's back (approximate exposure area of 6.25 cm^2) in the amount of 0.5 mL. The area of application was covered with a 2.5-cm x 2.5-cm gauze patch secured with paper tape, loosely overwrapped with Saran Wrap®, and secured with Elastoplast® tape to provide a semiocclusive dressing. Collars were not used to restrain the test animals during the 4-hour exposure period.

At the end of the 4-hour exposure period, the patches were removed and the test sites were washed using tap water and disposable paper towels. The test material was removed from the test sites as thoroughly as possible without irritating the skin.

Reason for Route of Administration

Historically, the dermal route has been the route of choice based on the method of Draize.[3]

Observations

Approximately 30 minutes after removal of the test material, the degree of erythema and edema at each test site was read according to the Draize technique (recorded as the 4-hour score). Subsequent examinations were made at 24, 48, 72, and 96 hours and Days 7, 14, and 21. The untreated skin of each animal was used for comparison.

Animals were weighed just before test material administration and at weekly intervals throughout the study.

Termination

At termination of the experimental phase, all animals were designated to be euthanized and discarded.

Statistical Analyses

No statistical analyses were required by the protocol.

Location of Raw Data, Records, and Final Report

The raw data, records, and a copy of the final report will be retained in the archives of HWI in accordance with HWI SOP.

Sample: T-5897

SUMMARY OF RESULTS

Test Animal: Albino Rabbits - Hra:(NZW)SPF
Source: HRP, Inc., Kalamazoo, MI
Date Animals Received: 03/09/94

Experimental Start Date: 03/16/94 Experimental Termination Date: 04/06/94

Individual Dermal Irritation Scores

Animal		Erythema								Edema							
		Hour					Day			Hour					Day		
Number	Sex	4	24	48	72	96	7	14	21	4	24	48	72	96	7	14	21
F50250	F	1	2	2[b]	2[b]	2[b]	1[d]	0	0	0	3	3	2	2	0	0	0
F50251	F	1	3[a,b]	4[n]	4[n]	4[n]	4[n]	2[x]	1[s]	1	4	4	2	2	1	1	1
F50252	F	2	3[a,b]	3[n]	4[n]	4[n]	4[n]	1[s,c]	0[s,c]	1	4	3	2	2	2	1	1

a Subcutaneous hemorrhaging.
b Blanching.
c Denuded area.
d Desquamation.
n Possible necrotic area.
s Possible scar tissue.
x Exfoliation.

Average Primary Dermal Irritation Scores*

Observation Period	Average Score
4 Hour	2.0
24 Hour	6.3
48 Hour	6.3
72 Hour	5.3
96 Hour	5.3
Day 7	4.0
Day 14	1.7
Day 21	1.0

* The average primary dermal irritation score is the total dermal irritation score for all the animals (erythema and edema) divided by the number of test sites (3) at each observation period.

DISCUSSION

Application of T-5897 to the skin of rabbits under 4-hour semioccluded conditions resulted in well-defined to severe erythema and moderate to severe edema reactions. Subcutaneous hemorrhaging, blanching, possible necrotic areas, desquamation, exfoliation, possible scar tissue, and denuded areas were also observed. Irritation continued to be present in two animals at the Day 21 observation.

REFERENCES

1. "Acute Dermal Irritation/Corrosion," *Organisation for Economic Cooperation and Development's Guidelines for Testing of Chemicals*, Section 404 (adopted May 12, 1981).

2. NIH Publication No. 86-23 (revised 1985).

3. Draize, J. H., "Primary Irritation of the Skin," In: *Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics - Dermal Toxicity*, Association of Food and Drug Officials of the U.S., pp. 46-47 (1959).

APPENDIX

Raw Data

HWI: 40202402

PERSONNEL SIGNATURE SHEET
ACUTE TOXICOLOGY

Name	Job Title	Signature	Initials
Rose M. Bridge	Report Supervisor	Rose M. Bridge	RB
Anthony Cass	Lab Animal Technician	Anthony Cass	AC
Cindy J. Cary, DVM	Lab Animal Veterinarian	Cindy J. Cary	CJC
Donna J. Clemons, DVM, MS	Lab Animal Veterinarian	Donna J. Clemons	DJC
John A. Disch	Lab Animal Caretaker	John A. Disch	JD
Charles W. Fritz	Lab Animal Technician	Charles W. Fritz	CF
Kari Garfoot	Lab Animal Technician	Kari Garfoot	KG
Steven M. Glaza	Manager	Steven M. Glaza	SG
Kevin Grossman	Lab Animal Caretaker	Kevin Grossman	KG
Jeff Hicks	Lab Animal Technician	Jeff Hicks	JH
Sharen L. Howery	Research Assistant	Sharen L. Howery	SLH
Wayne A. Madison	Supervisor	Wayne A. Madison	WAM
Doug McConnell	Lab Animal Technician	Douglas B. McConnell	DBM
Eileen McConnell	Staff Assistant	Eileen McConnell	EMM
Bud McDonald	Study Coordinator	Bud McDonald	BMcD
Albert Oleson	Lab Animal Caretaker	Albert Oleson	AO
Patricia Padgham	In-life Supervisor	Patricia Padgham	PP
Steven R. Sorenson	Study Coordinator	Steven R. Sorenson	SRS
Annette R. Turner	Staff Assistant	Annette R. Turner	ART
Tamra L. Walker	Staff Assistant	Tamra L. Walker	TW
Lana M. Weeden	Staff Assistant	Lana M. Weeden	LMW
Heather M. Weber	Lab Animal Caretaker	Heather M. Weber	HW
Janice Griffiths	Lab Animal Caretaker	Janice Griffiths	JG
Nikolai Larbalestier	Lab Animal Caretaker	Nik Larbalestier	NL
Pamela J. Kluth	Lab Animal Caretaker	Pamela J. Kluth	PJK
~~Carol Koch~~ (62/10-06-93)	Lab Animal Technician	Carol Koch	CK

HWI No.: 402024402

DERMAL IRRITATION/BODY WEIGHT RECORD (4-HOUR EXPOSURE)

Test Material: T-5897 (+27°C) Physical Description: VISCOUS CLOUDY WHITE LIQUID

Dose: 0.5 mL Per Site NA Moistened with 0.9% Saline; Mfg/Lot No./Exp. Date: NA / NA / NA

pH Result: U with Corning pH Meter No. 05510 Skin Preparation: ✓ Intact NA Abraded (with a clipper blade)

Species/Source Strain/Location: Rabbit/Hra:(NZW)SPF/ NW Date Animals Received: 3-9-94 Initiated in Room No.: 104

Technician/Date/Time Animals Clipped: KG 3-15-94 14:10

Animal Number/Sex	F5	02♂50	02♀51	02♀52				Technician	Recorded By	Date/94	Scale Used A ! D
Initial Body Weight (g)		2138	2012	2185				KG	KG	3/16	CS6044465
Day 7 Body Weight (g)		2362	2152	2303				ac	ac	3-23	CS6044465

Observations — **Irritation Score**

4 Hour	Erythema	1	1	2				KG	KG	3/16	✓ ac 3-23-94 2.0 KG 3-17-94
	Edema	0	1	1							
24 Hour	Erythema	2	3AB	3AB				KG	KG	3/17	✓ ac 3-23-94 6.3 KG 3-17-94
	Edema	3	4	4							
48 Hour	Erythema	2B	4N	3AB				KG	KG	3/18	✓ ac 3-23-94 6.3 KG 3-18-94
	Edema	3	4	3							
72 Hour	Erythema	2D	4N	4N				KG	KG	3/19	✓ ac 3-23-94 5.3 KG 3-19-94
	Edema	2	2	2							
96 Hour	Erythema	2B	4N	4N				KG	KG	3/20	✓ C7 3-25-94 5.3 ac 3-23-94
	Edema	2	2	2							
Day 7	Erythema	1D	4N	4N				ac*	ac	3-23	✓ C7 3-25-94 4.0 ac 3-23-94
	Edema	0	1	2							

D SPELLING ERROR. KG 3-15-94

Storage conditions of test material: FREEZER (REMOVED TO ~~REFRIG~~ REFRIGERATOR AT APPROXIMATELY 15:30 ON 3-15-94)

NA Not applicable. A Subcutaneous hemorrhage. U Unable to determine pH.
B Blanching. N Possible necrotic area.
D-Desquamation ac 3-23-94
* Animal(s) shaved prior to dermal observation by technician.
† - TEMPERATURE OF TEST MATERIAL PRIOR TO DOSING. KG 3-16-94

Animals were weighed and appeared normal before test material administration on the day of dosing. Technician/Date: KG 3-16-94

Surviving animals designated for sacrifice and discard. Technician/Date: NA / NA

(S2/12-09-92)

Final data review by/Date: JH / 3-26-94

HWI No.: 40202402

DERMAL IRRITATION/BODY WEIGHT RECORD (4-HOUR EXPOSURE)
(CONTINUED)

Test Material: T-5897

Animal Number FS	0250	0251	0252				Technician	Recorded By	Date 1994	Scale Used A&D
Day 14 Body Weight (g)	2531	2320	2389				ac	ac	3-30	CS6044465
Day 21 Body Weight (g)	2695	2484	2543				ac	ac	4-6	CS6044465
Day 28 Body Weight (g)										

Observations

Irritation Score

Day 14	Erythema	0	2^{X}	1^{SC}				ac*	ac	3-30	✓ K 4-2-94 1.7 ac 3-30-94
	Edema	0	1	1							
Day 21	Erythema	0	1^{S}	0^{SC}				ac*	ac	4-6	✓ C7 4-7-94 1.0 ac 4-6-94
	Edema	0	1	1							
Day 28	Erythema										
	Edema										
	Erythema										
	Edema										
	Erythema										
	Edema										

NA Not applicable.
A Subcutaneous hemorrhage.
B Blanching.
N Possible necrotic area.
X-exfoliation ac 3-30-94
S-possible scar tissue ac 3-30-94
C-Denuded area ac 3-30-94
* Animal(s) shaved prior to dermal observation by technician.

Surviving animals designated for sacrifice and discard. Technician/Date: ac / 4-6-94

(S4/12-09-92)

Final data review by/Date: C7, 4-7-94

HWI No.: 40202402

Primary Dermal Irritation Scoring Scale
(Draize Technique)

(1) Erythema and Eschar Formation

No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Highest possible erythema score	4

(2) Edema Formation

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges are well defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised approximately 1 mm and extending beyond area of exposure)	4
Highest possible edema score	4

(S5/01-07-91)